UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IRA BRIEF and CATHIE BRIEF, husband and wife, **Plaintiffs,** **v.** **IDELLE LABS, LTD. and JOHN DOE 1 through JOHN DOE 75 (fictitious),** **Defendants.**	Civ. No. 2:22-cv-05085 (WJM) **OPINION**

In this product liability action, Defendant Idelle Labs, Ltd. ("Defendant") moves to dismiss Plaintiffs' Ira Brief and Cathie Brief ("Plaintiffs") Second Amended Complaint ("SAC") for failure to state a claim upon which relief may be granted pursuant to Fed. R. Civ. P. 12(b)(6). ECF No. 39. The Court decides the matter without oral argument. Fed. R. Civ. P. 78(b). Upon careful review of the parties' submissions, for the reasons stated below, Defendant's motion to dismiss is **granted in part and denied in part**.

I. BACKGROUND

Plaintiff Ira Brief ("Mr. Brief") was diagnosed with Acute Myeloid Leukemia ("AML") on February 16, 2022. SAC, ¶ 70, ECF No. 34. Plaintiffs claim that Mr. Brief's AML was caused by exposure to benzene from the Sure® Unscented Aerosol Antiperspirant Deodorants that he bought and used from approximately 1985 through February 2022, including those with UPC 0088348400278 ("Sure Aerosols" or "Products"), Lot number 20280[1] with an expiration date of September 2022. *Id.* at ¶ 60. According to the CDC "Facts About Benzene" website cited in the AC, "[l]ong-term exposure to high levels of benzene in the air can cause leukemia." *Id.* at ¶¶ 41, 42.[2]

Plaintiffs filed suit on August 17, 2022 alleging product defect in violation of the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1, *et seq.* ("PLA"). By Opinion and Order filed April 10, 2023, the Court granted Defendant's motion to dismiss the Amended Complaint ("AC"). ECF Nos. 30, 31. Plaintiffs' manufacturing defect allegation was

[1] The UPC number references the general Secret product type rather than a specific batch, which is identified by lot number. The lot number is a unique code that a manufacturer assigns to a batch of products they have produced in the same run using the same ingredients, parts, and materials. SAC, ¶ 30.

[2] https://emergency.cdc.gov/agent/benzene/basics/facts.asp

dismissed with prejudice; however, as to the design defect and failure to warn claims, Plaintiffs were permitted to file a second amended complaint to cure their pleading defects. *See* April 10, 2023 Op. and Order. Plaintiffs filed their SAC on June 7, 2023, ECF No. 34.

In the SAC, Plaintiffs rely on a November 3, 2021 petition by Valisure, a third-party consumer protection organization, to the FDA to take action against high levels of benzene in antiperspirant and deodorant body sprays. *Id.* at ¶ 18. The petition was based on the results of testing conducted by Valisure ("Valisure Report") showing that benzene was detected at 2.00 ppm (FDA concentration limit) or higher in a variety of spray deodorant and antiperspirant products including three samples of Sure Aerosol identified by three different Lot numbers. SAC, ¶ 19. Valisure concluded that particularly "with body sprays, 'propellants' like butane, isobutane, propane, and alcohol are commonly used and could potentially be sources of benzene contamination." *Id.* at ¶ 20.

Shortly thereafter, on February 16, 2022, the FDA posted a voluntary recall notice from TCP HOT Acquisition LLC dba HRB Brands ("Company Announcement") of certain products including the Sure Aerosol with expiration dated "on or before August 2023." *Id.* at ¶ 22; www.brutsurerecall2022.com. The notice explains that while benzene is not an ingredient in any of the recalled products, "unexpected levels of benzene came from the propellant that sprays the product out of the can." *Id.* The Company Announcement recalled three additional products that were not included in the Valisure Report. *Id.* at ¶ 23-27; www.brutsurerecall2022.com. Prior to the recall, Mr. Brief possessed and had used Sure Aerosol with an expiration date of September 2022. *Id.* at ¶ 28.

Finally, the SAC contends that between May 24, 2023 through May 29, 2023, Eurofins MTS Consumer Product Testing US, Inc. ("Eurofins") conducted independent laboratory testing of four canisters of Sure Aerosol, Lot 20280, with an expiration of September 2022. *Id.* at ¶ 33. The results of the testing showed benzene levels of between 8 to over 11 ppm in each of the four canisters tested. *Id.*

Defendant now moves to dismiss the SAC for failure to properly plead design or warning defect under the PLA. Plaintiffs oppose the motion and alternatively, seek leave to amend.

II. DISCUSSION

A. Fed. R. Civ. P. 12(b)(6) Standard

Federal Rule of Civil Procedure 12(b)(6) provides for the dismissal of a complaint, in whole or in part, if the plaintiff fails to state a claim upon which relief can be granted. The moving party bears the burden of showing that no claim has been stated. *Hedges v. United States,* 404 F.3d 744, 750 (3d Cir. 2005). Dismissal is appropriate only if, accepting all the facts alleged in the complaint as true, the plaintiff has failed to plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly,* 550 U.S.

544, 570 (2007); *see also Umland v. PLANCO Fin. Serv., Inc.,* 542 F.3d 59, 64 (3d Cir. 2008). This assumption of truth is inapplicable, however, to legal conclusions couched as factual allegations or to "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements." *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). Although a complaint need not contain detailed factual allegations, "a plaintiff's obligation to provide the 'grounds' of his 'entitlement to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly,* 550 U.S. at 555. Thus, the factual allegations must be sufficient to raise a plaintiff's right to relief above a speculative level, *see id.* at 570, such that the court may "draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678 (citing *Twombly,* 550 U.S. at 556). While "[t]he plausibility standard is not akin to a probability requirement' ... it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.*

B. PLA

In its prior opinion dismissing the AC, the Court found that the Valisure Report and the single passing reference to possession of "recalled products," AC, ¶ 35, was insufficient for the Court to infer a defect, that is, the presence of benzene in the Products used by Mr. Brief. While the existence or "bare fact" of a voluntary recall does not prove a defect, *see Goldin v. Smith & Nephew, Inc.,* 2013 WL 1759575, at *4 (S.D.N.Y. Apr. 24, 2013), in contrast to the AC, which contained *no* factual allegations regarding any recall apart from the bare fact of its existence, *see* AC, ¶ 35, the SAC provides details of the February 16, 2022 Company Announcement including the fact that the recall was not limited to specific lot numbers of Sure Aerosols. SAC, ¶¶ 22-27. Given the broad recall of *all* Products with the expiration of "on or before August 2023" due to the presence of unexpected levels of benzene that *came from the propellant,* it is reasonable to infer on a motion to dismiss that the Products Mr. Brief used prior to the recall also may have contained benzene since they too were aerosol products.

Moreover, Plaintiffs' previous allegations of product defect in the AC rested primarily on the Valisure Report, which did not include testing of the specific Product batch that Mr. Brief purchased. Now, in contrast, the SAC alleges that testing by Eurofins discovered high levels of benzene in lot number 20280, the specific batch used by Mr. Brief until the February 16, 2022 recall notice. *See Huertas v. Bayer U.S., LLC,* No. 21-20021, 2023 WL 3773139, at *10 (D.N.J. May 23, 2023) (finding plaintiffs unable to establish plausible inference that product purchased by plaintiffs contained benzene at excessive levels where tested products did not match lot numbers of products purchased by plaintiff); *Rooney v. Procter & Gamble Co.,* No. 22-1164, 2023 WL 1419870, at *4 (E.D. La. Jan. 31, 2023) (holding plaintiffs failed to plausibly allege use of product containing benzene where Valisure "petition identifies the specific lot numbers of the batches that allegedly contained benzene, but plaintiffs do not allege that the cans [plaintiff] used have those lot numbers."). In addition, the Valisure Report does not indicate that there were any samples

of Sure Aerosols that tested lower than 2.00 ppm of benzene. *Cf. Rooney v. Procter & Gamble Co.*, No. CV 22-1164, 2022 WL 17092124, at *3 (E.D. La. Nov. 21, 2022) (noting that if all Secret samples tested by Valisure contained benzene, that "would make plausible plaintiffs' contention that the cans [plaintiff] used likewise contained benzene."). These allegations of representative testing support a reasonable inference of the presence of benzene in all of the Sure Aerosoles used by Mr. Brief since 1985. *See e.g., Kimca v. Sprout Foods, Inc.*, No. 21-12977, 2022 WL 1213488, at *5 (D.N.J. Apr. 25, 2022) (finding that allegations supported by representative testing established "plausible inference that every package of the Baby Food Products, including those purchased by Plaintiffs, contains the heavy metals" particularly at motion to dismiss stage).

Next, Plaintiffs now sufficiently pled causation to defeat a motion to dismiss. While Plaintiffs may ultimately have difficulty proving proximate cause in part due to the ubiquity of benzene,[3] at this juncture, accepting all the facts alleged in the complaint as true, Plaintiffs' factual contentions are enough for the Court to draw the reasonable inference that Mr. Brief's use of the Sure Aerosols over the years resulted in long-term exposure to high levels of benzene in the air that caused his AML. *See* SAC, ¶¶61-63.

1. *Design Defect*

"To establish a prima facie case of design defect, the plaintiff must assert that the product could have been designed more safely and present, under a risk-utility analysis, the existence of an alternative design that is both practical and feasible." *Barrett v. Tri-Coast Pharmacy, Inc.*, 518 F. Supp. 3d 810, 826 (D.N.J. 2021) (citing *Mendez v. Shah*, 28 F. Supp. 3d 282, 297 (D.N.J. 2014)). A "plaintiff must plead either that the product's risk outweighs its harm, or that an alternative design exists, in order to state a claim for a design defect under the PLA." *Id.* (citing *Smith v. Keller Ladder Co.*, 275 N.J. Super. 280, 284 (App. Div. 1994)).

Plaintiffs plead that the risk of cancer and possibly death outweigh the harm of being smelly and sweaty, SAC, ¶ 79, and also claim that instead of "utilizing the propellant that sprays the product out of the can that exposed the Plaintiff to benzene," one safer alternative design Defendant could have used was a "bag-on-value technology that separates the product inside the case." *Id.* at ¶ 78. As previously noted by the Court, Plaintiffs allege the existence of an alternative design, *see* April 10, 2023 Op., at 6, and that alternative formulations and designs were and are used by other manufacturers to produce deodorants and antiperspirants containing less than 2.00 ppm of benzene. *Id.* at ¶ 5. Since Plaintiffs have also now sufficiently pled that the Products Mr. Brief used were defective, *see* discussion above, Defendant's motion to dismiss the design defect claim is denied.

[3] Outdoor air contains low levels of benzene from "tobacco smoke, gas stations, motor vehicle exhaust, and industrial emissions" and indoor air contains higher levels from products "such as glues, paints, furniture wax, and detergents." https://emergency.cdc.gov/agent/benzene/basics/facts.asp.

2. *Failure to Warn*

An adequate warning is defined by statute as "one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product." N.J.S.A. 2A:58C-4. If the product contains an adequate warning or instruction, the manufacturer is not liable for harm caused by a failure to warn. *Id.* Where warnings "in connection with a drug" are approved by the FDA, there is a rebuttable presumption that those warnings are adequate. N.J.S.A. 2A:58C-4. Because Sure® antiperspirant spray products are regulated as drugs, SAC, ¶ 17, to rebut the presumption of adequacy, Plaintiffs must present "clear and convincing evidence that a manufacturer knew or should have known, based on newly acquired information, of a causal association between the use of the drug and "a clinically significant hazard" and that the manufacturer failed to update the label accordingly." *In re Accutane Litig.*, 235 N.J. 229, 275, 194 A.3d 503, 530 (2018). "'For all practical purposes, absent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive of such claims.'" *Vicente v. Johnson & Johnson*, No. 20-1584, 2020 WL 7586907, at *13 (D.N.J. Dec. 21, 2020) (citing *Perez v. Wyeth Labs., Inc.*, 161 N.J. 1, 25 (1999), amended, No. 20-1584, 2021 WL 2328159 (D.N.J. June 7, 2021)).

Plaintiffs maintain that Defendant "knew or should have known" that benzene in the Products posed a grave risk of harm as admitted in the February 2022 Company Announcement recall because the Valisure Report recognizes that the "hematotoxicity of benzene has been described as early as 1897." SAC ¶ 95, 96. That allegation, however, does not plausibly show when Defendant acquired such knowledge or that it was prior to Valisure's petition to the FDA on November 3, 2021. Further, Plaintiffs also argue that the Court should infer that Defendant acquired knowledge of the presence of benzene at least six years ago on November 15, 2015 due to "information contained" in a different class action, *Delcid v. TCP Hot Acquisition LLC*, No. 21-cv-09569 (S.D.N.Y.).[4] SAC, ¶ 97. However, *Delcid* was not filed until November 18, 2021, about two weeks after Valisure sent its November 3, 2021 petition to the FDA. *See Delcid v. TCP Hot Acquisition LLC*, No. 21-9569, 2023 WL 3144169, at *1 (S.D.N.Y. Apr. 28, 2023). Thus, Plaintiffs have not identified any facts in the SAC that support an inference that Defendant knew or should have known of the Products' benzene contamination and a link between use of its Products and leukemia based on "newly acquired" information. Nor do Plaintiffs plead *any* facts that demonstrate that "deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects" rendered any FDA compliant warnings inadequate. The failure to warn claim is **dismissed without prejudice**.

[4] In *Delcid,* the plaintiffs alleged failure to disclose the presence of benzene in certain antiperspirant and deodorant products. Pursuant to the settlement of that class action, purchasers of certain Sure and Brut brand products between November 15, 2015 and October 28, 2022 were eligible to receive a portion of their purchase price. *See* https://sureandbrutsettlement.com/. SAC, ¶ 97.

C. Punitive Damages

The PLA precludes an award for punitive damages if a drug "is generally recognized as safe and effective pursuant to conditions established by the federal Food and Drug Administration and applicable regulations, including packaging and labeling regulations" unless "the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question… ." N.J.S.A. § 2A:58C-5. A punitive damages claim is also governed by the New Jersey Punitive Damages Act, N.J.S.A. § 2A:15-5.9, which requires that a plaintiff prove "by clear and convincing evidence" that the defendant's acts or omissions caused the harm and "were actuated by actual malice or accompanied by a wanton and willful disregard of persons who foreseeably might be harmed by those acts or omissions." N.J.S.A. § 2A:15–5.12. "Actual malice" is defined as "an intentional wrongdoing in the sense of an evil-minded act." N.J.S.A. § 2A:15–5.10. "Wanton and willful disregard" is defined as "a deliberate act or omission with knowledge of a high degree of probability of harm to another and reckless indifference to the consequences of such act or omission." *Id.*

Plaintiffs conclude that Defendant knowingly withheld or misrepresented information to the FDA by withholding the results of independent testing that Plaintiffs believe occurred because only three months after Valisure's petition to the FDA, Defendant recalled two Sure products rather than only the product identified in the Valisure Report. Since malice and willful disregard is a "fact-specific inquiry requiring examination of Defendant's intent and knowledge, … it is a judgment that is ill-suited for a motion to dismiss." *Daloisio v. Liberty Mut. Fire Ins. Co.*, 754 F. Supp. 2d 707, 710 (D.N.J. 2010). Defendant's motion to dismiss the punitive damages claim is **denied.**

III. CONCLUSION

For the reasons noted above, Defendant's Fed. R. Civ. P. 12(b)(6) motion to dismiss is **granted in part and denied in part**. The failure to warn claim is **dismissed without prejudice**. Defendant's motion to dismiss the claims for design defect and punitive damages is **denied.** Plaintiffs' request for leave to file a third amended complaint, which is included in their opposition brief and does not include a draft amended complaint to show that the amendment would cure the deficiency, is **denied**. *See Cureton v. Nat'l Collegiate Athletic Ass'n*, 252 F.3d 267, 273 (3d Cir. 2001) ("court may deny a request if the movant fails to provide a draft amended complaint").

WILLIAM J. MARTINI, U.S.D.J.

Date: September 14, 2023